First Named Inventor: Weston F. Harding
Application No.: 10/828,964
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#### **REMARKS**

This Amendment is in response to the Office Action dated December 26, 2008, in which all of the pending claims (32-37) were rejected. With this Amendment, claims 32-37 are presented for reconsideration and allowance.

## **Specification**

The specification is amended to correct an inadvertent numbering error. Specifically, the paragraph numbers are amended to include the first paragraph and therefore, match the paragraph numbers of U.S. Pub. No. 2004/0199126. This amendment to the specification contains no new matter.

### **Drawings**

In the Office Action, the drawings were objected to under 37 CFR 1.83(a) as failing to show every feature of the invention specified in the claims. Specifically, the "portion of the slit in the distal portion of the septum is open in the unstressed condition" is identified as absent from the drawings. The objection under 37 CFS 1.83(a) is respectfully traversed. Examiner is directed to FIGS. 40 and 42. FIG. 40 depicts distal portion 23 of septum 20 having an elliptical cross section and slit 25 being open in an unstressed condition. Note FIG. 40 is similar to FIG. 37, but with slit 25 being open in an unstressed condition. FIG. 42 depicts distal portion 23 of septum 20 having a circular cross section and slit 25 being open in an unstressed condition. Note FIG. 42 is similar to FIG. 38, but rotated 90 degrees and with slit 25 being open in an unstressed condition. The drawings show every feature specified in the claims and thus, the 1.83(a) objection should be withdrawn.

# Claim Rejections – 35 USC § 112

In the Office Action, claims 34 and 37 were objected to under 35 USC § 112, 1<sup>st</sup> paragraph, as failing to comply with the written description requirement. The rejection of claims 34 and 37 under 35 USC § 112 is respectfully traversed. Claims 34 and 37 are supported by Figures 40 and 42, as well as the specification as published (page 8, columns 15-16, paragraph 88). As

explained in paragraph 88 of the specification, distal portion 23 of septum 20 can be either circular or elliptical in cross section and slit 25 can be either closed or open. FIG. 39 depicts distal portion 23 of septum 20 having an elliptical cross section and slit 25 being closed. FIG. 40 depicts distal portion 23 of septum 20 having an elliptical cross section and slit 25 being open. As explained above, FIG. 40 is similar to FIG. 37, but with slit 25 being open in an unstressed condition. FIG. 41 depicts distal portion 23 of septum 20 having a circular cross section and slit 25 being closed. FIG. 42 depicts distal portion 23 of septum 20 having a circular cross section and slit 25 being open. As explained above, FIG. 42 is similar to FIG. 38, but rotated 90 degrees and with slit 25 being open in an unstressed condition. The claims are fully supported by the application and thus, the §112 rejection should be withdrawn.

## Claim Rejections - 35 USC § 102

In the Office Action, claims 32-33 and 35-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by McPhee (U.S. Patent No. 5,199,948), hereinafter McPhee '948. Claims 32-37 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Jepson et al. (U.S. Pat. No. 6,344,033), hereinafter Jepson '033.

In claims 32-34, the distal portion 23 of the septum 20 has a substantially circular cross-section, and the distal portion of channel 13 formed by top portion 12 of housing 10 has a substantially elliptical shape. As a result, the distal portion 23 of the septum 20 is biased to a substantially elliptical shape by the distal portion of the channel 13. This biasing of the distal portion 23 of the septum 20 causes a portion of longitudinal slit 25 in the distal portion 23 of the septum 20 to be closed. The biasing of the circular distal portion 23 of the septum 20 to a closed position is illustrated in FIG. 38, while an open unstressed state is depicted in FIG 42.

In claims 35-37, the distal portion 23 of the septum 20 has a substantially elliptical cross-section, and the distal portion of channel 13 formed by the top portion 12 of the housing 10 has a substantially circular cross-section. As a result, the distal portion 23 of the septum 20 is biased into a substantially circular shape by the distal portion of the channel 13 and a portion of the longitudinal slit 25 in the distal portion 23 of the septum 20 is closed. The biasing of the elliptical distal portion

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23 of the septum 20 to a closed position is illustrated in FIG. 37, while an open unstressed state is depicted in FIG. 40.

Unlike the present invention, as defined in claims 32-37, McPhee '948 does not configure the housing 13 to bias the longitudinal slit 33 at the distal end of the septum 15. Instead, biasing forces are applied at the proximal end of the septum 15 to close the longitudinal slit 33 at its proximal end. In McPhee '948, both the septum 15 and the upper portion of the housing 13 have circular cross sections. The closing of the longitudinal slit 33 occurs simply by the press fit of the circular cross section septum 15 into the circular cross section upper portion of the housing 13. Since McPhee '948 fails to teach or suggest a needleless luer access connector where either the distal portion of the channel formed by the top portion of the housing, or the distal portion of the septum, is elliptical in cross-section to bias closed the longitudinal slit in the distal portion of the septum, claims 32-37 are patentable over this reference.

Jepson '033 also fails to teach or suggest configuring the housing 26 to bias longitudinal slit 46 at the distal end of septum 28. In FIGS. 3, 3A, 5 and 5A, Jepson '033 illustrates lower portion 40 of septum 28 being substantially rectangular in horizontal cross section. The Office Action points to FIG. 13, however, in FIG. 13 lower portion 410 is conically shaped and sealed to housing 418. Since Jepson '033 also fails to teach or suggest a needleless luer access connector where either the distal portion of the channel formed by the top portion of the housing, or the distal portion of the septum, is elliptical in cross-section to bias the longitudinal slit in the distal portion of the septum, claims 32-37 are patentable over this reference.

#### **Double Patenting**

In the Office Action, a nonstatutory double patenting rejection was also made. The Office Action stated "Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-37 of U.S. Patent Nos. 6,908,459." It appears that the Office Action reversed the claims, and that claims 32-37 of the present application were being rejected over claims 1-7 of U.S. Patent No. 6,908,459. Regardless, a terminal disclaimer is

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submitted with this Amendment to obviate the double patenting rejection and thus, the rejection should be withdrawn.

### Conclusion

In conclusion, this Amendment has placed the application in condition for allowance. Notice to that effect is requested.

Respectfully submitted, KINNEY & LANGE, P.A.

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